FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd. East, Hyattsville, Maryland
January 10, 2018

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss whether the safety of Tlando has been adequately characterized. If additional safety data are needed, discuss the type(s) of data that are needed and whether these data should be obtained pre-approval or whether these data can be obtained post-approval. Specifically cover:

    a. The effects of Tlando on cardiovascular risk factors, including blood pressure and lipids, together with effects on hematocrit, and the potential for Tlando to increase the risk of adverse cardiovascular outcomes in the population that will likely use the drug if it is approved. Specifically comment on whether ambulatory blood pressure monitoring is needed pre-approval.

    b. Supraphysiologic dihydrotestosterone (DHT) concentrations in some subjects.

    c. Subjects with maximal testosterone concentrations (C_{max}) exceeding the prespecified targets.

    d. The adrenal-related findings, including adrenocorticotropin (ACTH) stimulation results.

2. **DISCUSSION:** Discuss whether the stopping criteria for use in clinical practice will appropriately identify patients who require discontinuation of Tlando.

3. **DISCUSSION:** Discuss whether testosterone concentrations measured in serum tubes are reliable in patients treated with Tlando.

4. **VOTE:** Is the overall benefit/risk profile of Tlando acceptable to support approval as a testosterone replacement therapy?

    Provide a rationale for your vote.